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09/673,937	10/24/2000	Toshiyuki Baba	00117	9019

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EXAMINER	
MELLER, MICHAEL V	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 2

Application Number: 09/673,937
Filing Date: October 24, 2000
Appellant(s): BABA ET AL.

Mail 02.12.04

Ronald Greigg
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/24/2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The appellant's statement in the brief that certain claims do not stand or fall together is noted; however, appellant has neither provided rationale to support the statement nor proposed subsets of the claims to stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,450,232	Sanford et al.	5-1984
5,814,473	Warren et al.	9-1998
5,804,402	De Giorgio et al.	9-1998
JP 08187095	Naoko et al.	7-1996
JP 60-224498	Fujio	11-1985

Segal et al., Biochemical and Biophysical Research Communications, vol. 30, no. 1, 1968, pgs, 63-68.

Segal et al., Symposium on Pyridoxal Enzymes, 1968, pgs. 37-42.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 28-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The is a "new matter" rejection.

In claim 29 the phrase, "wherein the concentration of the valine is 0.5 to 50 mmol/L" does not find support in the instant specification. The specification supports using valine at 0.5 to 100 mmol/L when valine is used alone but not the claimed range.

The same problem is in claim 42, where applicant has claimed using proline less than 100 mmol/L and not less than 0.5 mmol/L. The application provides support for 0.5 to 500 mmol/L only when using proline alone. The specification is very clear about this.

Similar problems are in claims 48 and 61.

Claims 28-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segal et al. (Symposium on Pyridoxal Enzymes-Segal 1-see table) in combination with Segal et al. (Biochemical and Biophysical Research Communications-Segal 2-see table) in view of JP 08187095 (abstract) and JP 60-224499 (abstract) and further in view of Sanford et al. (col. 1) , De Giorgio et al. (col. 1) or Warren et al. (col. 1).

The Segal references each teach that alanine aminotransferase is stabilized with proline. The references teach that the amount of proline used is 0.1 M. They do not

teach to stabilize aspartate aminotransferase with valine or proline. Segal 1 also teaches that valine can also be used to stabilize the enzyme at 0.1 M.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use less than 0.1 M of proline or valine since adjusting parameters to optimize the results of the invention is clearly within the purview of the skilled artisan and to adjust the amounts to the other concentrations claimed would also have been obvious since the skilled artisan uses routine experimentation to optimize the paramenters in an effort to optimize the desired results of the claimed invention. To stabilize another enzyme such as aspartate aminotransferase would have been obvious since this enzyme is so closely related to alanine aminotransferase since they are both amino acid transferases. Attension is drawn to Sanford et al., De Giorgio et al. and Warren et al. who all teach how interchangeable the enzymes are and that they are used in similar ways.

Further, to use the two amino acids together (valine and proline) would have been obvious since Segal 1, teaches that valine also has a high level of stability on alanine aminotransferase. To use valine alone is also obvious since Segal 1 uses valine alone to test the stability of the enzyme and yields a high result.

To use the specific serums or buffers would also have been obvious since the primary references (Segal 1 and 2) do use buffers and JP 08187095 and JP 60-224499 teach that serum albumin can be used to stabilize enzymes.

(11) Response to Argument

Concerning the 35 USC 112 rejection, appellant argues that this rejection was not brought up earlier. The outstanding rejection under 35 USC 112, first paragraph, is for the introduction of new matter in appellant's amendment filed 11/21/2002. The rejection was made as a result of the new matter introduced at that time.

Applicant alleges that they have support for "wherein the concentration of the valine is 0.5 to 50 mmol/L" (claims 29, 48 and 61) and where applicant has claimed that the "concentration of the proline is less than 100 mmol/L and not less than 0.5 mmol/L" (claim 42). The specification supports using valine at 0.5 to 100 mmol/L when valine is used alone but not the claimed range. The application also provides support for 0.5 to 500 mmol/L only when using proline alone. The specification is very clear about this.

Appellant points the examiner to tables and parts of the specification but nowhere is there any disclosure of the claimed ranges. Appellant could simply limit the claims to that which was described in the specification or to the exact points in the tables if they wish but they simply do not have support for such ranges as claimed.

Concerning the 35 USC 103 rejection, appellant argues that the references do not teach that both valine and proline were used in the same solution to stabilize the enzyme. The examiner never alleged this. It is noted that valine or proline were used separately, but to use them together would have been obvious because of the noted stabilizing effects each one had individually.

Next appellant argues each reference individually stating what the reference lacks. This was a rejection under 35 USC 103, not 35 USC 102. The reasons that the references were used were very clearly stated and thus it is apparent that they teach the claimed invention.

The Segal references provide the main teaching that proline and valine are known to be used to stabilize alanine transferase using buffers and albumin as claimed. The Japanese references show that albumin is known to be used to stablize enzymes. The US Patents were cited to show that alanine transferase and aspartate aminotransferase are used interchangeably all the time, especially in clinical settings.

Thus, it was made very clear in the rejection that since one knows that you can use both enzymes interchangeably, that the two amino acid are both known to stabilize the same enzyme and that albumin is well known to be used to stabilize enzymes then it would have been obvious to practice the claimed invention.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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MVM
February 4, 2004

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